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31498	7590	03/12/2009	EXAMINER	
DURECT CORPORATION THOMAS P. MCCrackEN 2 RESULTS WAY CUPERTINO, CA 95014			FRAZIER, BARBARA S	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of #11:

Applicant's arguments filed 2/17/09 have been fully considered but they are not persuasive for overcoming the outstanding rejections.

1. Regarding the provisional rejection of claims 1-8, 10-13, 15, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-37 of copending Application No. 11/183,477: In response to Applicant's arguments that the alleged conflicting claims have not in fact been granted, said condition of claims is already noted; accordingly, the claims are **provisionally** rejected. In response to Applicant's request that the provisional rejection continue to be held in abeyance until allowable subject matter has been determined in the present application, it is noted that neither application has been allowed and both applications are currently still pending; therefore, the provisional rejection stands for reasons stated in the previous final Office action mailed 11/10/08.

2. Regarding the rejection of claims 1-8, 10-13, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement: upon further reconsideration of Applicant's specification and the cited prior art of record, it has been determined that Applicants have described in the specification the subject matter of the claims in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, when the specification is considered in light of the prior art of record. Accordingly, the rejection is withdrawn.

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would have been in possession of the subject matter of claim 1

3. Regarding the rejection of claims 1-8, 10-13, 15, and 17 under 35 U.S.C. 103(a) as being unpatentable over Berry et al (WO 00/45790) and Chen et al (US 2003/018036), in combination alone or further in view of Kasraian et al (Pharm. Dev. And Tech., 4(4) 475-480, 1999) and Hunt (US 2003/0064536): Applicant's arguments have been fully considered but are not deemed persuasive for overcoming the rejection for reasons set forth below.

Applicants argue that Berry notes the adverse effects of peroxides with lipid vehicles in the prior art, and offers a solution to the problems with reactive species such as peroxides by using certain polymer formulations instead of lipid vehicles. Applicants argue that Berry's avoidance of peroxide problems with the polymer formulations "is in stark contrast to the assertion by the Office that it was obvious to treat a polymer vehicle, using applicants' recited methionine washing procedure to arrive at applicant's critical maximum peroxide value of 5 ppm or less". Applicants argue that Berry fails to fails to teach or suggest the desirability and thus the obviousness of applicants' recited formulations that contain a polymer vehicle that has been treated in a specific manner to arrive at a peroxide value of 5 ppm or less, and that Berry actually teaches away from applicants' recited invention.

This argument is not persuasive because the Office action does not state that the formulation of Berry and Chen is made by washing with methionine (contrary to Applicant's characterization), but that, given the teachings in Berry that adverse problems with peroxides have been solved with the use of its polymer formulations, one

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skilled in the art would expect the peroxide values of the formulations of Berry and Chen to be less than 5 ppm, especially given the fact that the components and use of the compositions of Berry and Chen are the same as the claimed invention. Indeed, by Applicant's own admission, peroxide values are minimized in the formulations of Berry (see page 11 of Applicant's response). It is further noted that the limitation "the polymer was treated with methionine" is a product-by-process limitation. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP 2113. In the instant claims, the limitation of treating the polymer with methionine to reduce peroxide values does not appear to impart a structural limitation to the formulation, other than the amount of peroxide values. Said amount would be obvious in light of the teachings of Berry et al, *supra*. Thus, the product-by-process limitation of "the polymer was treated with methionine in an amount sufficient to reduce vehicle peroxide values below 5 ppm" does not appear to impart a structural limitation different from that already disclosed in the product of Berry and Chen.

In response to Applicant's arguments that there is nothing in Kasraian and Hunt that leads back to the primary references and nothing in the primary references that would lead to Kasraian or Hunt, it is noted that primary references as well as Kasraian and Hunt are all drawn to injectable drug formulations, and are thus are within the same field of endeavor. Additionally, Kasraian specifically teaches the benefits of controlling the level of peroxide impurities with PVP, and Hunt specifically teaches the use of methionine to control peroxide impurities, and therefore both references are also drawn

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to solving the same problem, i.e., removal of peroxide impurities. Therefore, a skilled artisan would have employed the stable polymers in Berry, and would have been further motivated to stabilize them (as taught by Kasraian) by many ways, including treatment with methionine, as taught by Hunt.